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(54) **DEVICES AND METHODS FOR CONTROLLING EXPANDABLE PROSTHESES DURING DEPLOYMENT**

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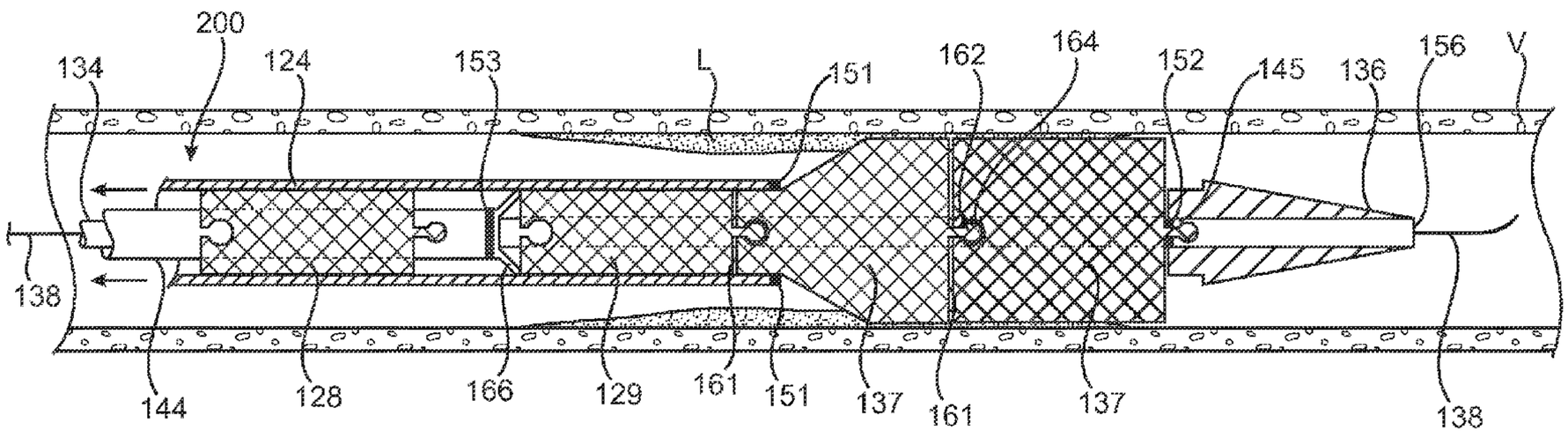
(57) **ABSTRACT**

A catheter for delivering a prosthesis to a treatment site in a body lumen comprises an elongate flexible member and a sheath slidably disposed thereover. A plurality of self-expanding tubular prostheses are carried in axially spaced apart locations along the elongate member, within the sheath. The prostheses may be selectively interlocked with one another and are constrained by the sheath in a radially contracted configuration. The prostheses are separately releasable from the sheath when the sheath is retracted relative to the elongate member. The catheter also has a pusher member slidably disposed along the elongate member within the sheath. The pusher is adapted to move past the prostheses in a first direction without displacing the prostheses, while in a second direction the pusher engages a selected prosthesis so as to move the prosthesis with the pusher to interlock the selected prosthesis with a second prosthesis.

26 Claims, 10 Drawing Sheets



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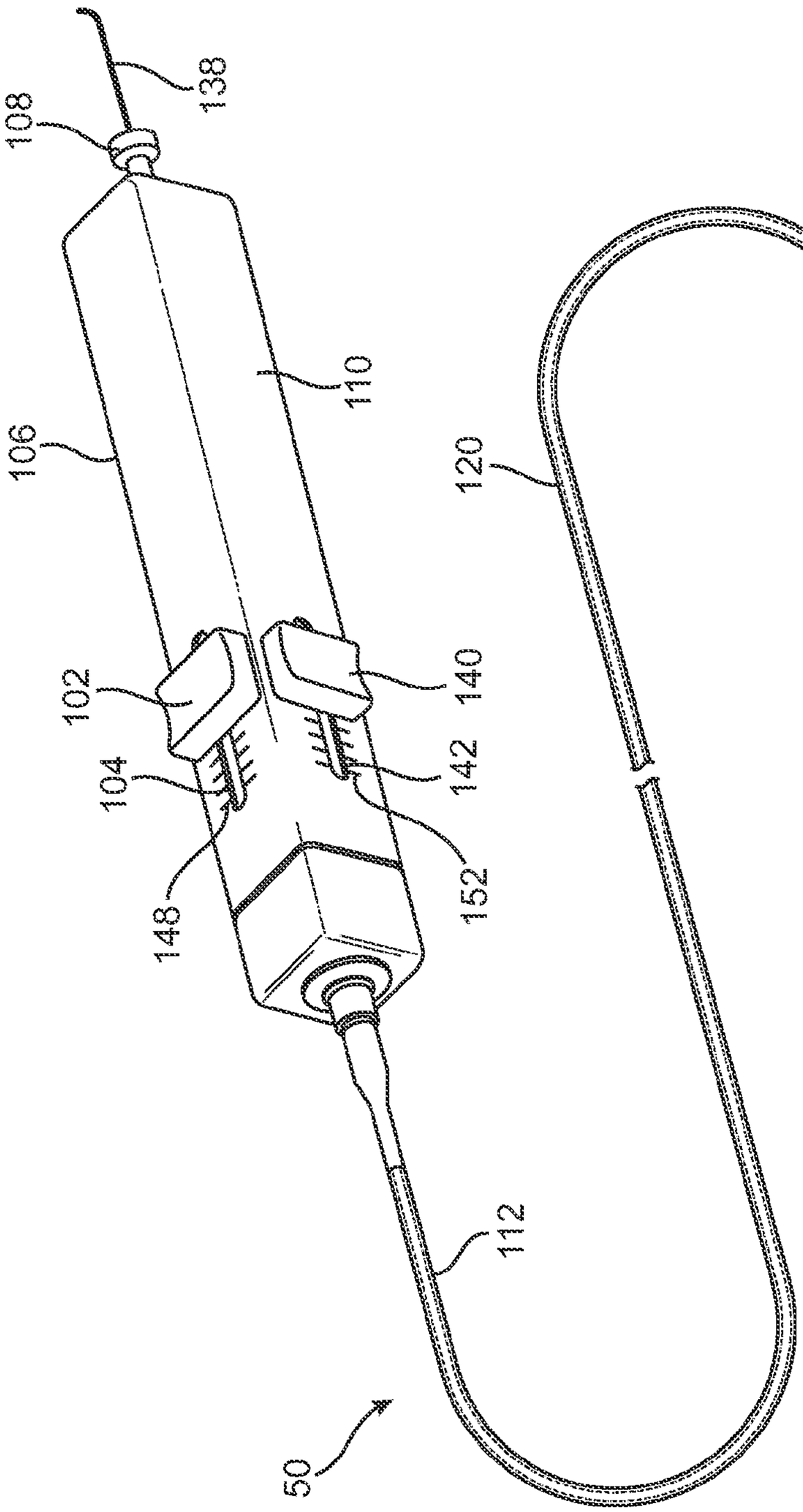
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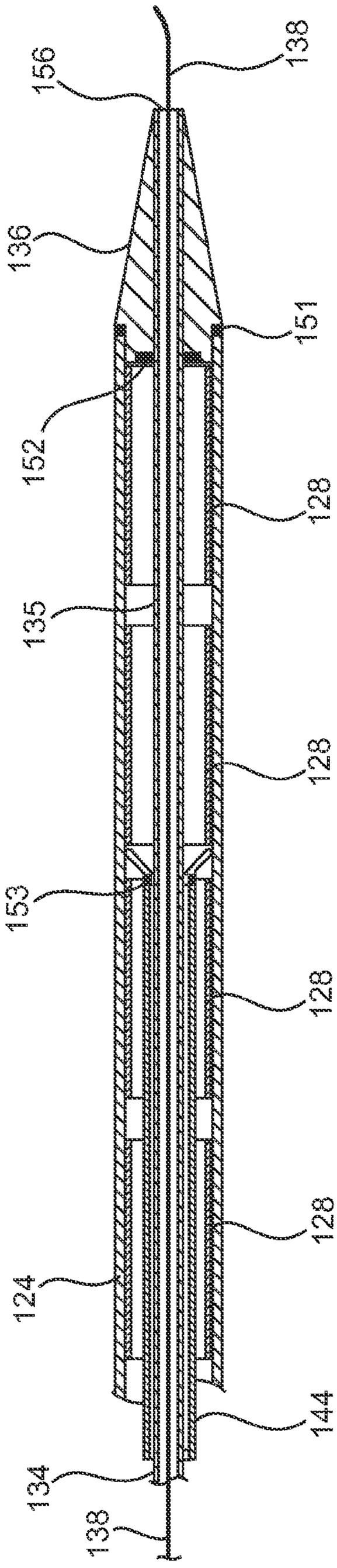
FIG. 1A



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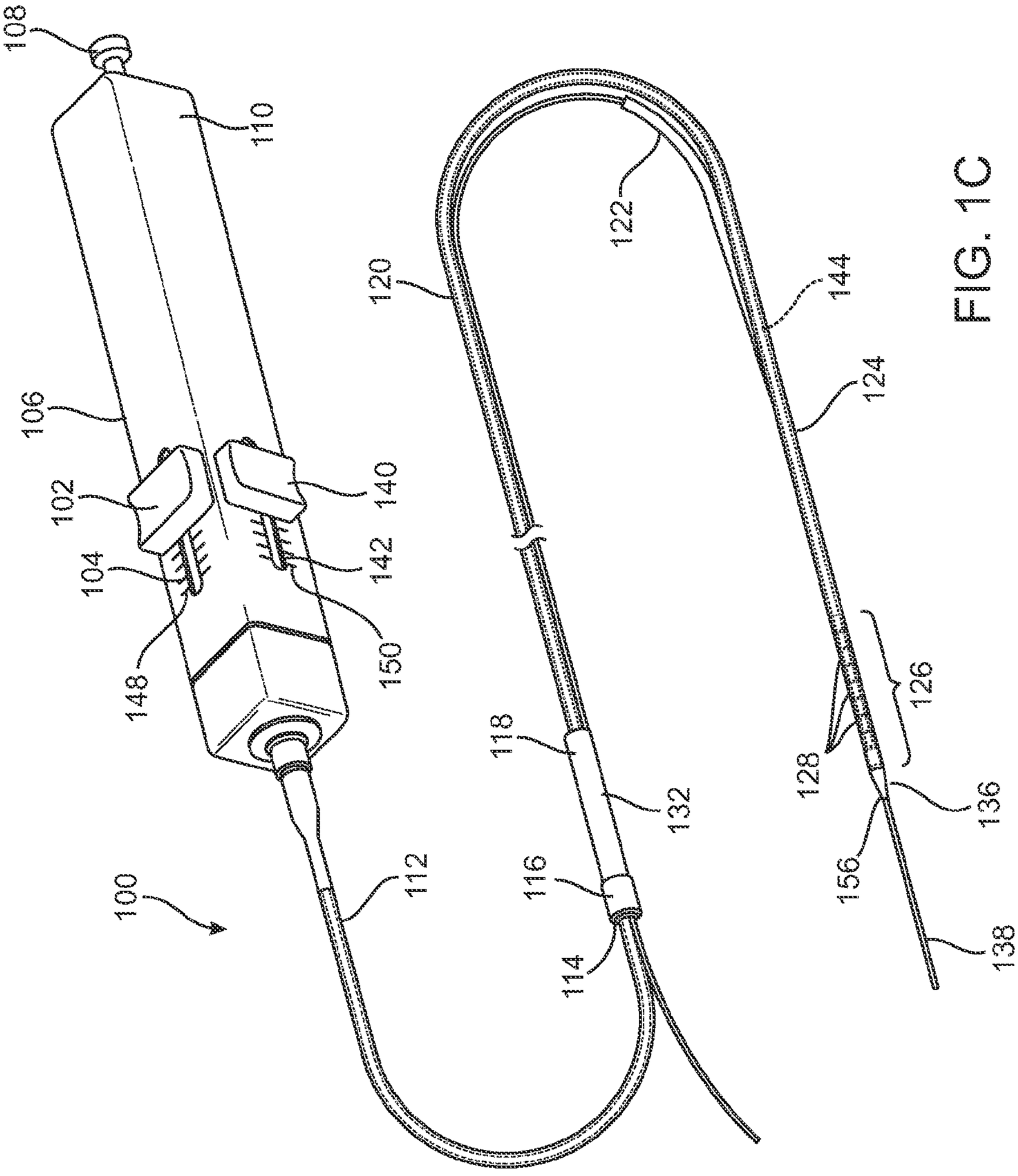
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FIG. 1C

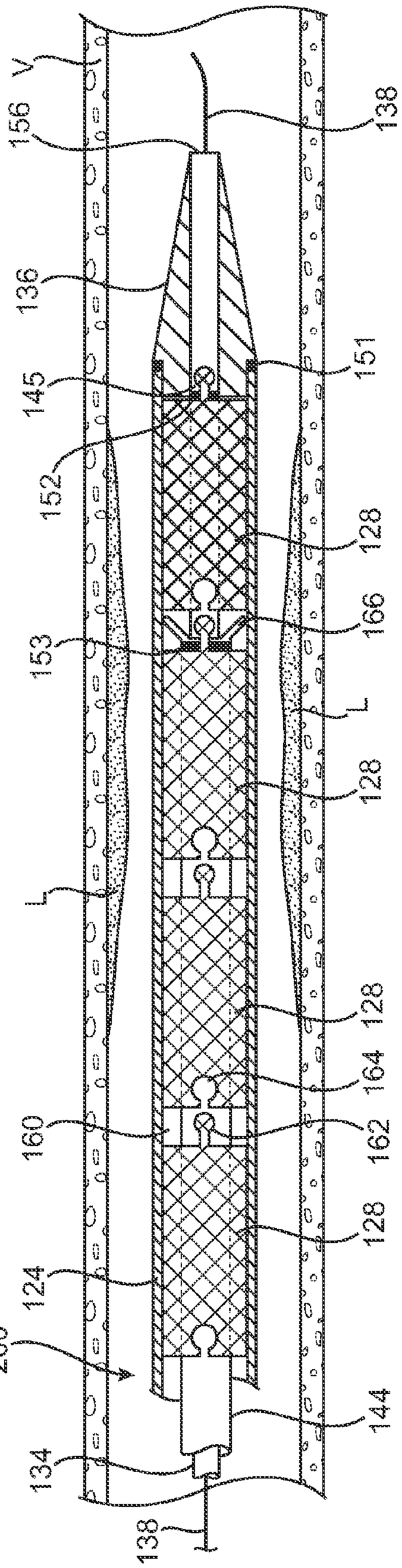
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FIG. 2A

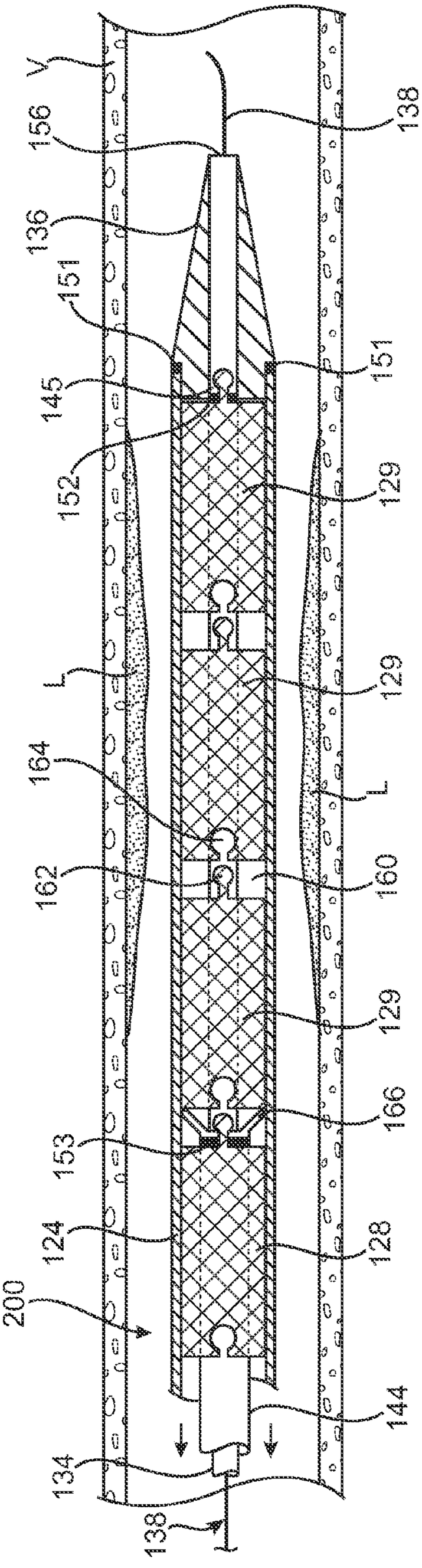
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FIG. 2B

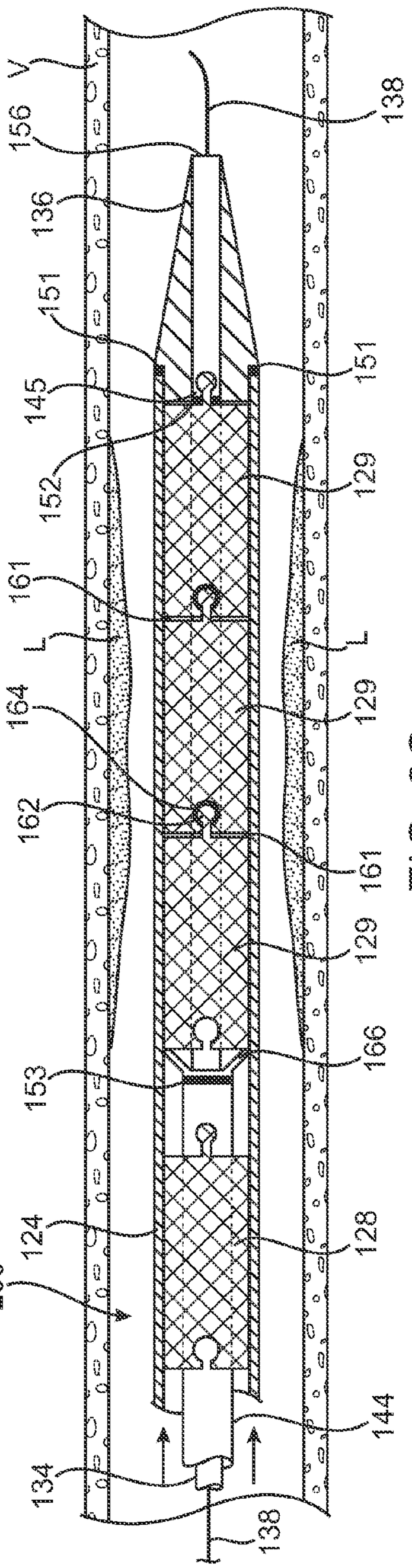
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FIG. 2C

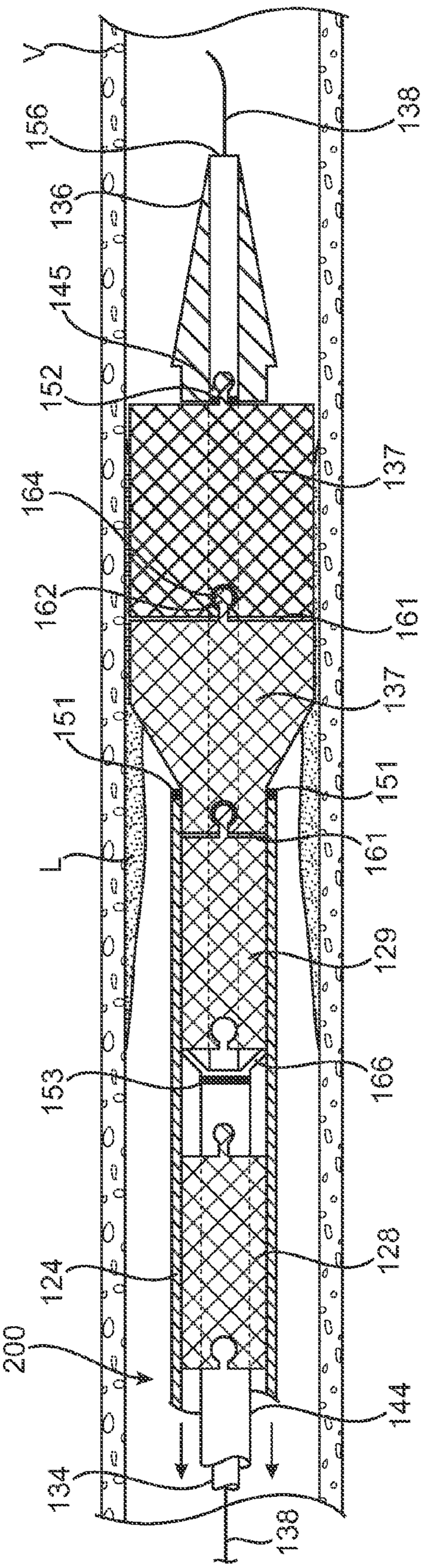
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FIG. 2D

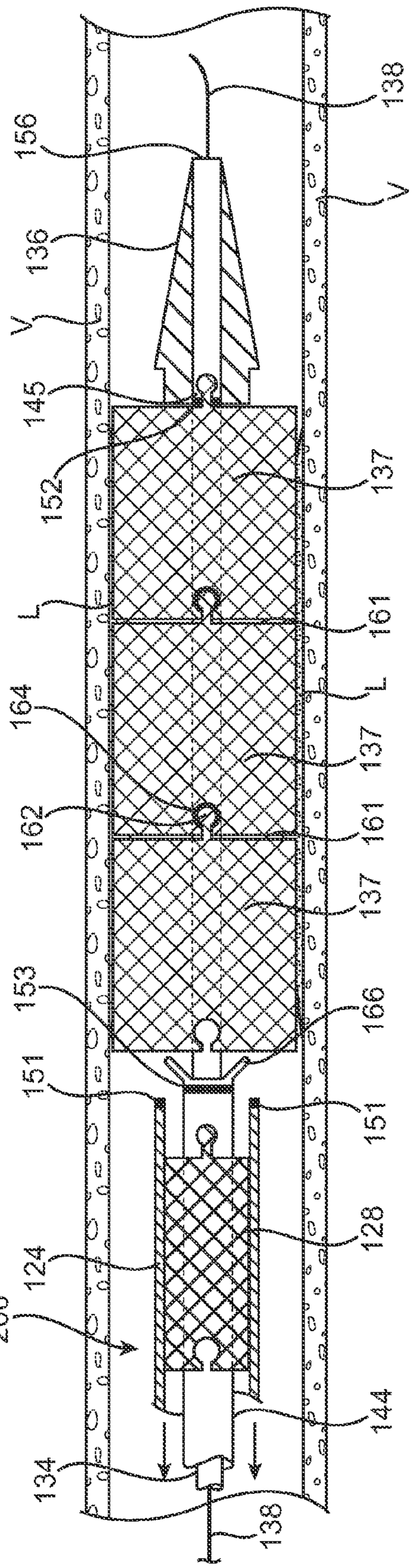
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FIG. 2E

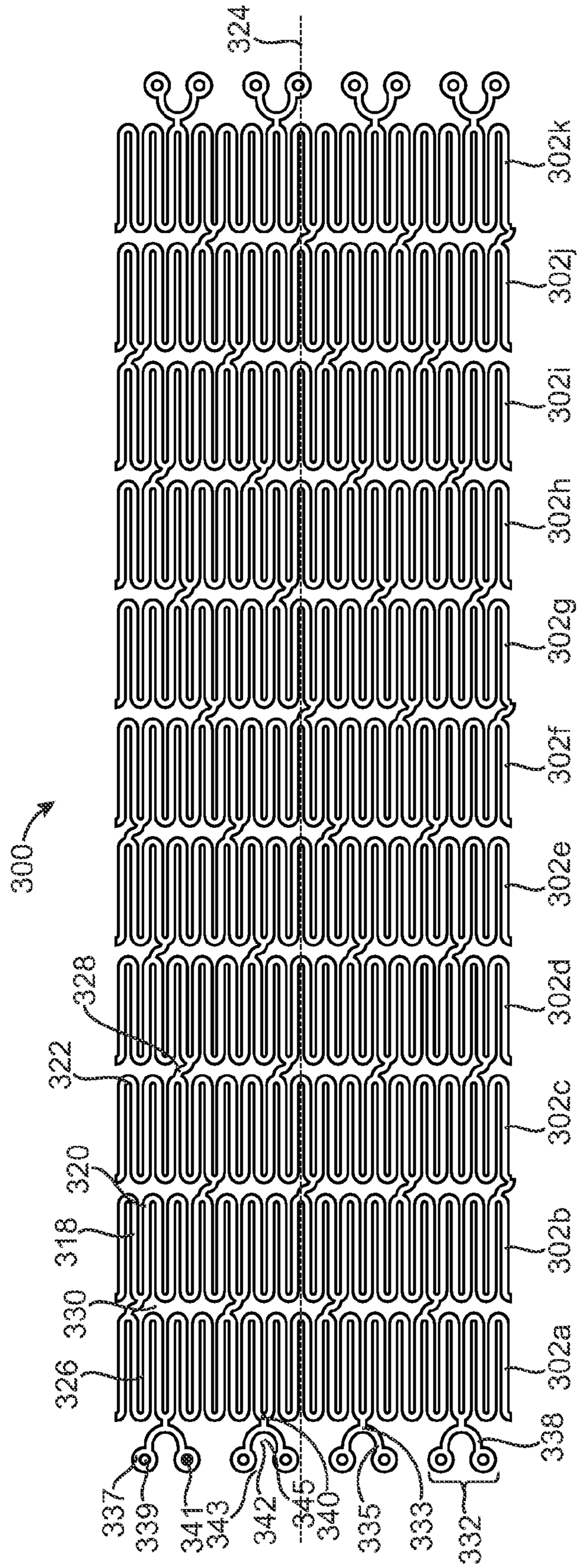
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FIG. 3A

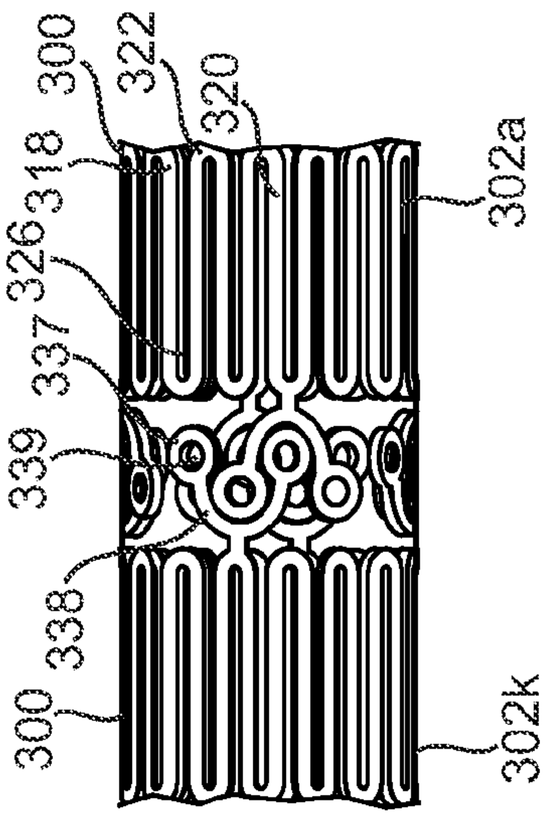
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FIG. 3B

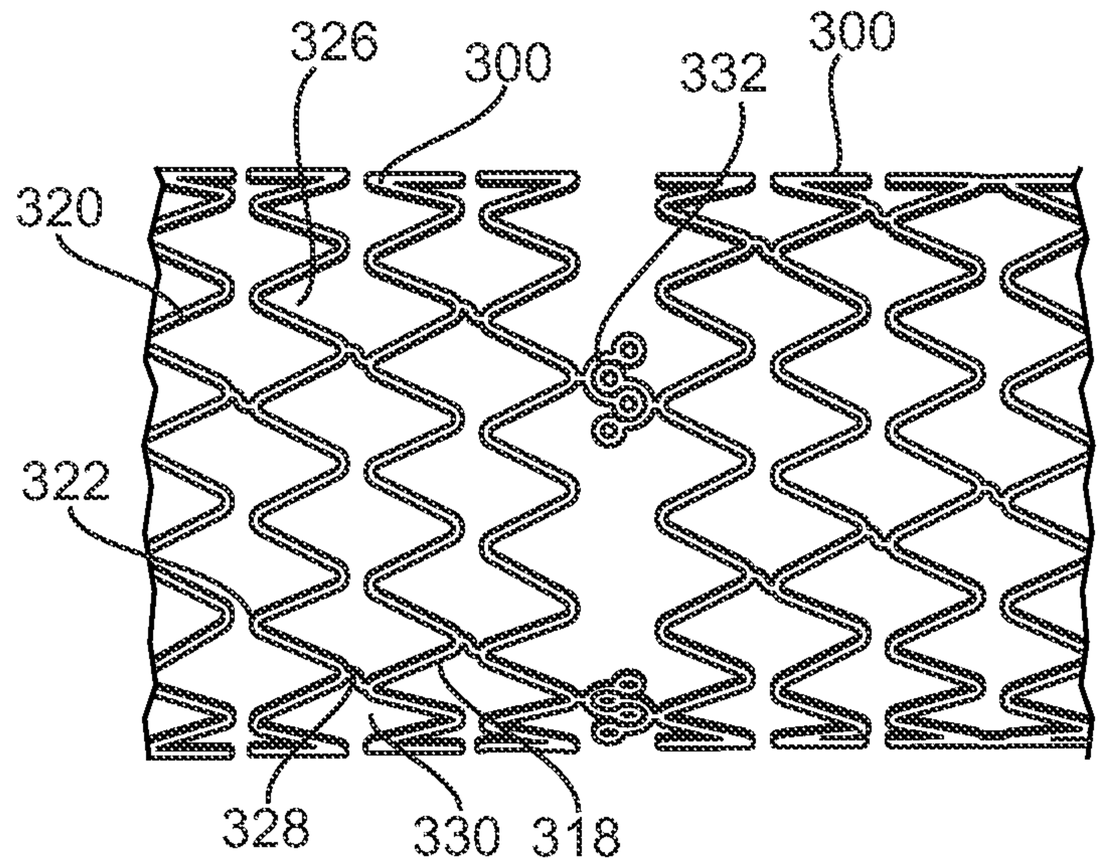
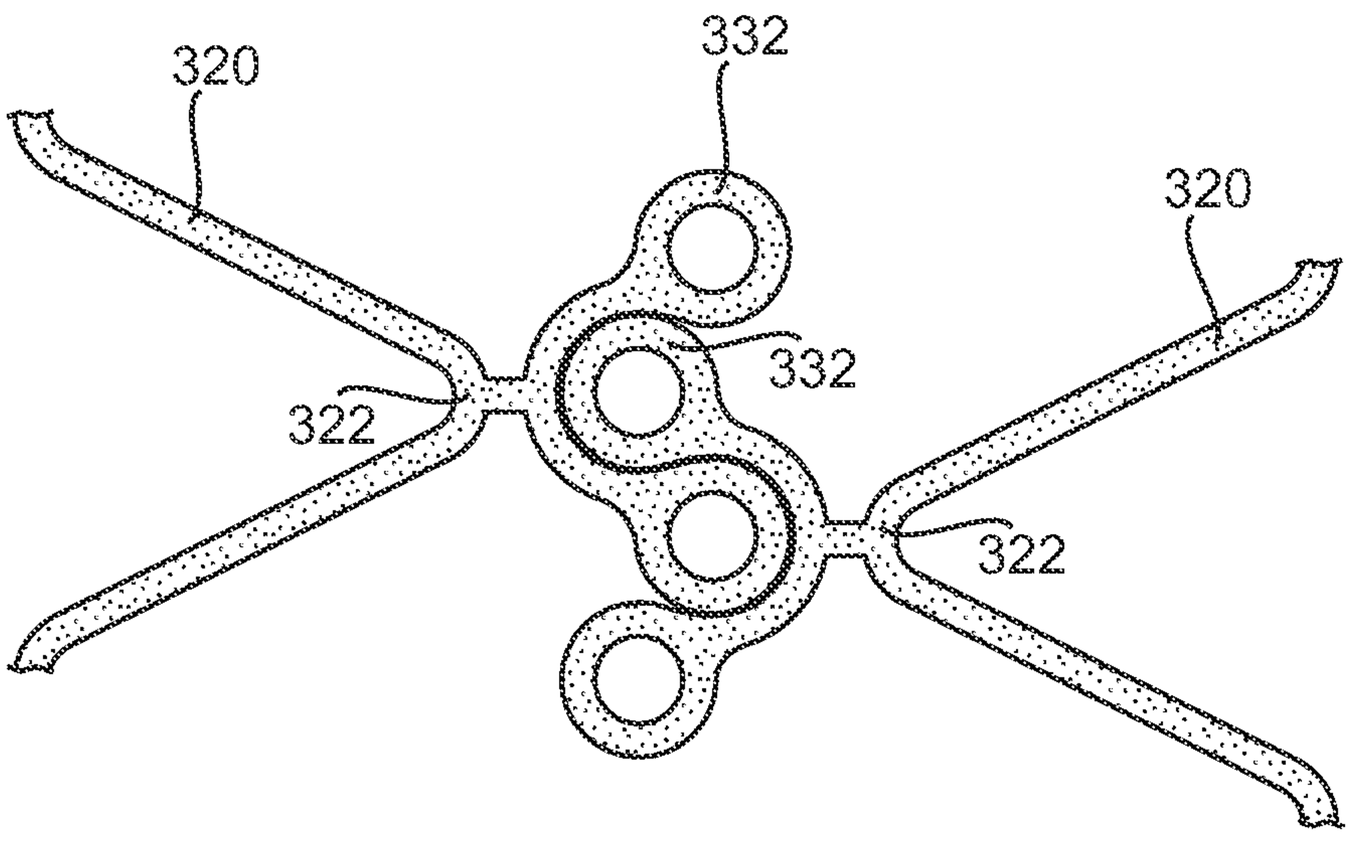


FIG. 3C



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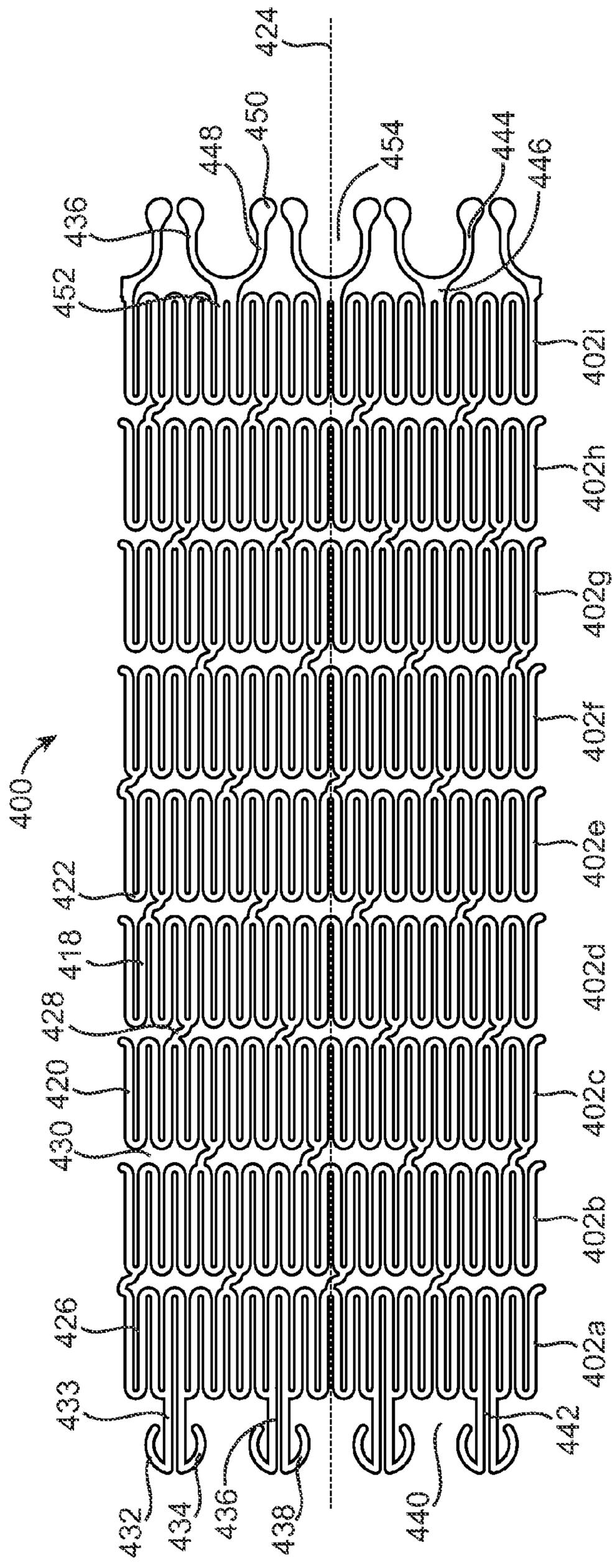
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FIG. 4A

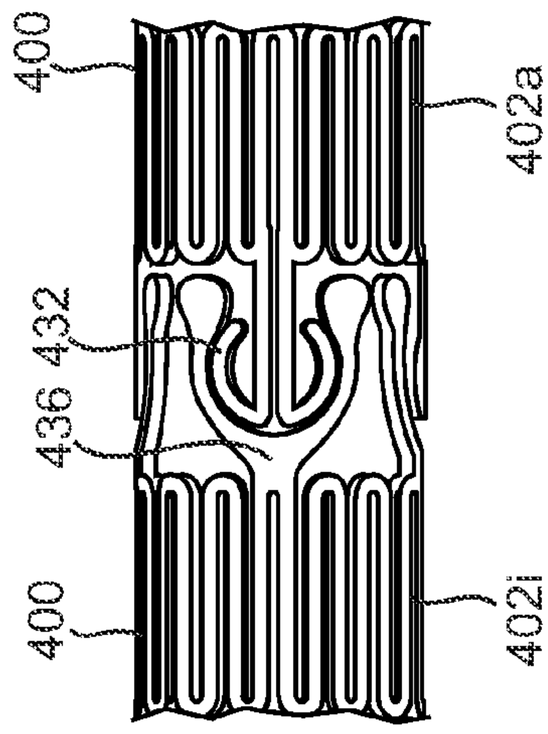
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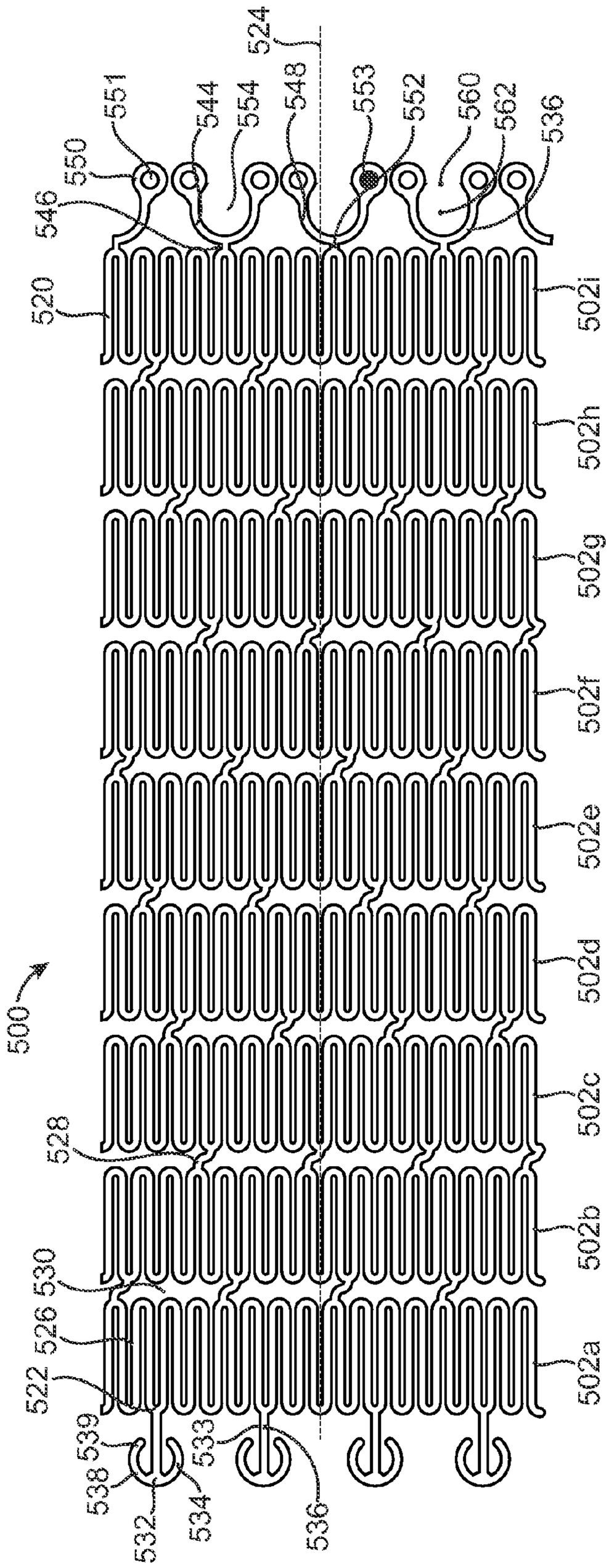
FIG. 4B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536

FIG. 5A

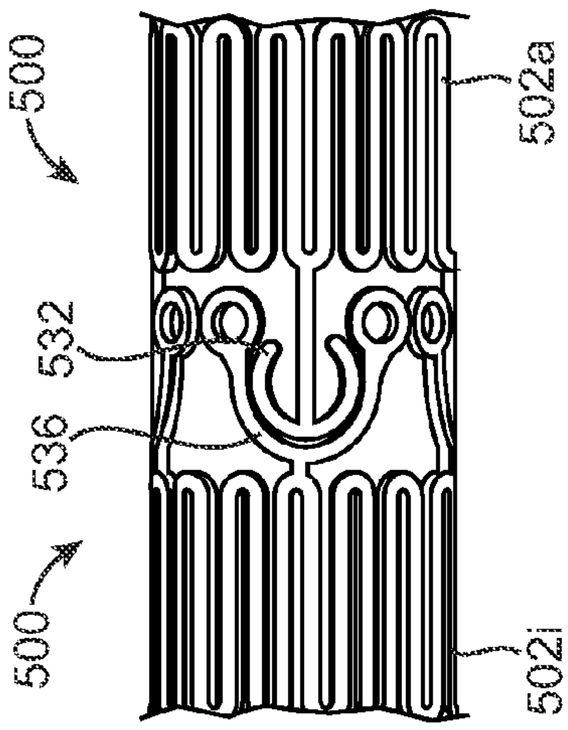
500
502a
532
536
500
502i

FIG. 5B

DEVICES AND METHODS FOR CONTROLLING EXPANDABLE PROSTHESES DURING DEPLOYMENT

CROSS-REFERENCES TO RELATED APPLICATIONS

NOT APPLICABLE

STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

NOT APPLICABLE

REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK

NOT APPLICABLE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to medical apparatus and methods, and more specifically to vascular catheters, stents and stent delivery systems for use in the coronary and peripheral arteries as well as other vessels and body lumens.

Stenting is an important treatment option for patients with occlusive disease in the vasculature as well as other systems such as the biliary tract. The stenting procedure involves placing a tubular prosthesis at the site of a lesion, typically within a diseased artery. The procedure is performed in order to maintain the patency of the artery and is often performed after a primary treatment such as angioplasty. Early stent results suffered from high rates of restenosis, i.e. the tendency for the stented vessel, such as an artery, to become re-occluded following stent implantation. However, in recent years, restenosis rates have decreased substantially, due to many improvements in stent delivery, stent technology as well as the use of drugs. As a result, the number of stent related procedures being performed worldwide continues to dramatically increase.

Stents are typically either self-expanding or balloon expandable and they are delivered to the arteries using long, flexible vascular catheters typically inserted percutaneously through the patient's femoral artery. For balloon expandable stents, the stents are usually mounted over a balloon on the delivery catheter, thus, when the balloon is inflated, it expands which correspondingly expands and deforms the stent to the desired diameter. The balloon can then be deflated and removed, leaving the stent in place. For self-expanding stents, the stent is released from the delivery catheter and it resiliently expands into engagement with the vessel wall. Self-expanding stents are often used in the peripheral vascular system since they are more resilient than balloon expandable stents. Resilient stents are better suited for implantation into regions of the body closer to the body's surface, such as a peripheral artery, since the stent's resilience helps minimize damage or crushing caused by body movement or externally applied forces.

Self-expanding stents may also be used in the coronary arteries and may provide advantages over balloon expandable stents. Balloon expandable stents are typically expanded with a balloon having a constant diameter and therefore the expanded stent may not conform well to a coronary artery having variations in diameter due to tortuosity or taper. Therefore, there is a potential for gaps between the outer stent surface and the inner surface of the artery wall. These gaps may lead to thrombus formation and recently, there has been concern that this effect is pronounced in drug eluting stents because the drug delays endothelialization of the stent surface, allowing the gaps to remain for a longer period of time. Self-expanding stents expand until the outer stent surface is constrained by contact with a vessel wall. Therefore, gaps between the stent and the arterial wall are minimized thus helping to reduce thrombus formation. Companies such as Devax (Irvine, Calif.) and Cardiomind (Sunnyvale, Calif.) are developing self-expanding stents for implantation into the coronary arteries.

Current stent delivery technology suffers from a number of drawbacks which can make delivery of stents challenging. In particular, current stent delivery catheters often employ stents having fixed lengths. The proper selection of fixed length stents requires accurate knowledge of the lesion length being treated. While lesion length may be measured prior to stent deployment using angiography and fluoroscopy, these measurements are often inaccurate. Thus, if an incorrectly sized stent is introduced to a treatment site, it must be removed from the patient along with the delivery catheter and replaced with a different device having the correct stent size. This prolongs the procedure, increases waste and results in a more costly procedure.

Additionally, and especially in the case of peripheral vascular disease, lesions are often long and diffuse. A single long stent may be deployed to treat a single lesion or to span multiple lesions, however this is not optimal since longer stents tend to have higher fracture and restenosis rates as compared with shorter stents. Therefore, placement of multiple shorter stents in a long lesion may be advantageous instead of deploying a single long length stent.

The use of "custom length" stents as an alternative to fixed length stents has been proposed. One such approach for providing a custom length stent has been to use segmented stents for treatment in which only some of the stents are deployed for treatment. Several exemplary systems are described in several copending, commonly assigned applications which are listed below. In these systems, the stent segments are deployed by selective advancement over the delivery catheter. After delivering an initial group of segments, the catheter may be repositioned to a new treatment site and a further group of segments can then be deployed. These systems enable treatment of multiple lesions with a single device and may contain up to fifty segments.

While this technology represents a significant improvement over earlier stent delivery systems, in the case of self-expanding stents, accurate delivery of the stents to a treatment site can present other challenges. Because self-expanding stent segments tend to rapidly spring open upon deployment, it is difficult to control their placement. In some cases, the stents may actually eject or "watermelon seed" away from the delivery catheter. Therefore, a delivery system that allows more precise control of stent deployment and placement is desirable.

Another challenge with existing "custom length" stent delivery systems is that to deliver multiple stent segments to multiple lesion sites requires an intricate delivery system that can be somewhat complex to use. Thus, a simpler delivery system that allows length customization is desirable, especially for use in treating long lesions in the peripheral and coronary vasculature.

For the reasons above, as well as others, it would be desirable to provide improved prosthetic stents and delivery catheters. It would be particularly desirable to provide catheters

which enable stent length to be customized using multiple stent segments. It is also desirable to provide a delivery system that is flexible and can track torturous vessels and that has a simple construction and is less costly and easy to use in deploying a selectable number of stent segments to a treatment site. It is further desirable to provide a stent delivery catheter that can control the delivery and placement of self-expanding stents in the peripheral and coronary vascular system.

2. Description of the Background Art

Prior publications describing catheters for delivering multiple segmented stents include: U.S. Publication Nos. 2004/0098081, 2005/0149159, 2004/0093061, 2005/0010276, 2005/0038505, 2004/0186551 and 2003/013266. Prior related unpublished co-pending U.S. patent applications include Ser. No. 11/148,713, filed Jun. 8, 2005, entitled "Devices and Methods for Operating and Controlling Interventional Apparatus"; Ser. No. 11/148,545, filed Jun. 8, 2005, entitled "Apparatus and Methods for Deployment of Multiple Custom-Length Prosthesis"; Ser. No. 11/344,464, filed Jan. 30, 2006, entitled "Apparatus and Methods for Deployment of Custom-Length Prostheses"; Ser. No. 60/784,309, filed Mar. 20, 2006, entitled "Apparatus and Methods for Deployment of Linked Prosthetic Segments"; Ser. No. 11/469,773 filed Sep. 1, 2006, entitled "Custom Length Stent Apparatus"; and Ser. No. 11/462,951, filed Aug. 7, 2006, entitled "Custom Length Stent Apparatus." The full disclosures of each of these patents and applications are incorporated herein by reference.

BRIEF SUMMARY OF THE INVENTION

The invention generally provides for the delivery of self-expanding prostheses with a flexible delivery catheter capable of navigating vessels such as the peripheral and coronary arteries. The delivery catheter permits controlled deployment of a selectable number of prosthetic segments at a treatment site, thus allowing customization of prosthesis length while the delivery catheter is in a body lumen at a treatment site. Customization of prosthesis length in situ permits better matching of the prosthesis length to the lesion length being treated.

The terms "stent" and "stenting" are defined to include any of the array of expandable prostheses and scaffolds which are introduced into a lumen at a target treatment site and expanded in situ thereby exerting a radially outward force against the lumen wall. The prosthesis of the present invention comprises a closed or an open lattice structure and is typically fabricated from an elastic material or self-expanding material, including superelastic materials such as nickel-titanium alloys like Nitinol, or spring temper stainless steels or polymers, and the lattice structures are commonly constrained radially during delivery and upon deployment the constraining structure is removed, allowing the prosthesis to "self-expand" at the target site. The terms "stent," "prosthesis," "prosthetic segment" and "stent segment" refer broadly to all radially expansible stents, grafts, and other scaffold-like structures which are intended for deployment within a body lumen.

In a first aspect of the present invention, a catheter for delivering a prosthesis to a treatment site in a body lumen comprises an elongate flexible member having a proximal end and a distal end. A sheath is slidably disposed over the elongate flexible member and a plurality of self-expanding tubular prostheses are carried in axially spaced-apart locations along the elongate flexible member, within the sheath. The plurality of self-expanding tubular prostheses are adapted to be selectively interlocked with one another and they are constrained by the sheath in a radially contracted configuration. The prostheses are separately releasable from the sheath as the sheath is retracted relative to the elongate flexible member.

The catheter also includes a pusher member that is slidably disposed along the elongate flexible member within the sheath and the pusher is adapted to move past the prostheses in a first direction, usually without displacing the prostheses. In a second direction, the pusher member engages a selected prosthesis and the pusher can move the prosthesis so as to interlock the selected prosthesis with a second prosthesis. The pusher member may have an engagement member which is deflectable radially inward by contact with the prostheses when moved in the first direction while in the second direction the engagement member engages the prostheses selected for deployment. Sometimes the engagement member may comprise a plurality of flexible fingers that extend radially outward from the pusher member. The pusher member often may exert substantially greater axial force against the plurality of self-expanding tubular prostheses when the pusher member is advanced distally than when the pusher member is retracted proximally.

Sometimes the catheter comprises a stopping element that is axially disposed along the elongate flexible member. The stopping element is adapted to prevent the plurality of self-expanding tubular prostheses from being displaced past the distal end of the elongate flexible member when the pusher member is advanced distally. The catheter may also comprise a handle that is usually near the proximal end of the elongate flexible member and the handle usually has a control mechanism adapted to move the sheath and pusher member. Sometimes the catheter may also include a central lumen disposed within the elongate shaft that can carry a guidewire.

In another aspect of the present invention, a method for delivering a prosthesis to a body lumen having a lesion with a length comprises introducing into the body lumen one or more self-expanding tubular prostheses. The prostheses are carried at axially spaced apart locations along an elongate flexible member and they are constrained in a contracted configuration within a sheath. Selecting a first group of the tubular prostheses for delivery picks a first group of prostheses that has a combined length substantially traversing the lesion. Bringing the first group into engagement with each other within the sheath interlocks prostheses in the first group with one another and uncovering the first group from the sheath removes the constraint from the first group so they may expand at the first treatment site while a second group of prostheses is retained within the sheath. Sometimes the method may further comprise selecting one or more additional self-expanding tubular prostheses and bringing them into to engagement with the first group within the sheath so that the additional prostheses interlock with the first group.

Selecting a first group of prostheses may comprise proximally retracting a pusher member. The pusher member often has a flexible engagement member that is deflected by the prostheses as the pusher member is retracted proximally. Bringing the first group into engagement with each other may comprise engaging at least one of the first group of prostheses with a pusher member and advancing the pusher member distally. Bringing the first group into engagement with each other may also comprise stopping the first group of prostheses from moving distally with a stopping element that is disposed on the elongate flexible member. Engaging the at least one prosthesis may include engaging the prosthesis with a flexible engagement member that is disposed on the pusher member and uncovering the first group can involve proximally retracting the sheath. The method may also comprise releasing a

therapeutic agent from the first group of prostheses after expansion at the treatment site. Often, the therapeutic agent may comprise an anti-restenosis agent.

In still another aspect of the present invention, a self-expanding tubular prosthesis comprises a plurality of self-expanding tubular rings that have a plurality of axial struts and a plurality of connectors coupling adjacent struts together. The axial struts and connectors also may form a plurality of substantially parallel and spaced apart columns of open cells. The axial struts and connectors often form a substantially zig-zag pattern and a bridge member couples adjacent tubular rings together. A plurality of bridges, which may be sigmoidally shaped may join the columns of open cells or rings together. Sometimes the connectors are U-shaped and often the columns of open cells are out of phase with an adjacent column. The prosthesis is usually adapted to be interlocked with an adjacent prosthesis when pressed together and the prostheses remain interlocked with one another even after radial self-expansion. The prosthesis often may have an interlocking tab on one end of the tubular rings that is adapted to interlock with an adjacent tubular ring when the rings are pressed together.

The interlocking tab may comprise a strut that defines an aperture which is adapted to hold a radiopaque marker. The bridge may be coupled to a connector and have an axially extending strut that joins the bridge with the connector. The bridge may connect to an apex of the connector, which may be U-shaped. The interlocking tab may comprise a narrow neck region and an enlarged head region which may be C-shaped. The enlarged head region may have an arcuate strut defining a narrow inlet portion and a wider receiving portion. The receiving portion is usually adapted to receive and interlock with an interlocking tab on an adjacent ring.

The enlarged head region may have a plurality of arcuate struts that are coupled to the ring with a plurality of axial struts and the neck region may comprise a plurality of axial struts. The enlarged head region may also comprise an arcuate strut that forms a C-shape and that is coupled to the ring with an axial strut.

The prosthesis may also have a female receiving tab on an end of the prosthesis opposite of the interlocking tab. The female tab may include an arcuate strut that defines a receptacle, sometimes C-shaped, which can receive and interlock with an enlarged head of an adjacent prosthesis. The arcuate strut may be coupled to a ring with an axial strut. The female tab may also comprise an arcuate strut that defines an aperture which can hold a radiopaque marker. The prosthesis may further comprise a therapeutic agent that is carried on the prosthesis and that may be released therefrom. Often, the therapeutic agent comprises an anti-restenosis agent. The prosthesis often has an overall length in the range from about 5 mm to about 50 mm. Sometimes each of the prostheses have the same length, although sometimes at least one of the prostheses may have a different length than another of the prostheses.

These and other embodiments are described in further detail in the following description related to the appended drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a perspective view of an over-the-wire stent delivery catheter in accordance with one embodiment of the present invention.

FIG. **1**B is a cross section of the distal end of the stent delivery catheter illustrated in FIG. **1**A.

FIG. **1**C is a perspective view of a stent delivery catheter in accordance with another embodiment of the present invention.

FIGS. **2**A-**2**E illustrate selection and deployment of prostheses in accordance with an exemplary embodiment.

FIG. **3**A shows a top view of a prosthesis after it has been unrolled and flattened.

FIG. **3**B shows interlocking of two of the prostheses illustrated in FIG. **3**A.

FIG. **3**C shows interlocking of two of the prostheses illustrated in FIG. **3**A after expansion.

FIG. **3**D highlights the interlocking of prostheses shown in FIG. **3**C.

FIG. **4**A shows a top view of another embodiment of a prosthesis after it has been unrolled and flattened.

FIG. **4**B shows interlocking of two of the prostheses illustrated in FIG. **4**A.

FIG. **5**A shows a top view of still another embodiment of a prosthesis after it has been unrolled and flattened.

FIG. **5**B shows interlocking of two of the prostheses illustrated in FIG. **5**A.

DETAILED DESCRIPTION OF THE INVENTION

In the drawings like numerals describe substantially similar components. Referring now to FIG. **1**A, a preferred embodiment of an over-the-wire prosthesis delivery catheter **50** comprises a catheter shaft **120** which includes a sheath **124** slidably disposed over a pusher tube **144** which is in turn slidably disposed over an inner shaft **134** (seen in FIG. **1**B). A prosthesis **126** is carried near the distal end of the catheter shaft **120** and is covered by sheath **124**. Pusher tube **144** is adapted to move past the prosthesis **126** in one direction and to push prosthesis **126** in a second direction and this will be described in greater detail below. A tapered nosecone **136** having a distal exit port **156**, composed of a soft elastomeric material to minimize trauma to the vessel during advancement of the delivery catheter **50**, is attached to the inner shaft **134** distally of the prosthesis **126**. Prosthesis **126** preferably comprises a plurality of self-expanding prostheses **128** mounted under sheath **124** and disposed over inner shaft **134**. Sheath **124** covers the self-expanding prostheses **128** and constrains them in a radially contracted configuration until the delivery catheter **50** has been properly positioned at a treatment site. A radiopaque marker **152** (FIG. **1**B) near the proximal end of nosecone **136** or optionally a radiopaque marker **151** near the distal end of sheath **124** and a radiopaque marker **153** near the distal end of pusher tube **144** help the operator visualize the delivery catheter under a fluoroscope during a stent procedure. Radiopaque marker **153** also helps the operator to view the distance the pusher **144** has been retracted relative to the radiopaque marker **152** adjacent to nosecone **136**. This helps the operator determine how many prostheses **128** to deploy and will be discussed in greater detail below.

As shown in FIG. **1**A, handle **106** is attached to a proximal end **112** of the outer sheath **124**. The handle **106** performs several functions, including retracting and advancing outer sheath **124** and pusher tube **144** thereby allowing selection and exposure of prosthetic segments **128** so that they may self-expand and be deployed. A guidewire **138** is positioned slidably through adapter **108** of handle **106** and extends through inner lumen **135**, exiting distal port **156**.

Handle **106** includes a housing **110** which encloses the internal components of the handle **106**. Handle **106** allows a physician operator to advance or retract outer sheath **124** and pusher tube **144**. The amount of retraction of sheath **124** and

pusher tube **144** determine the number of individual prostheses **128** to be deployed thereby establishing the overall length of the prosthesis **126** while ensuring accurate delivery of the individual prostheses **128**. The inner shaft **134** is preferably fixed to the handle housing **110**, while both outer sheath **124** and pusher tube **144** are coupled to slide mechanisms **102** and **140**, respectively. Slide mechanisms **102** and **140** allow both the outer sheath **124** and pusher tube **144** to be retracted and advanced relative to handle **106**. Optionally, a single slide mechanism could be used to control motion of the outer sheath **124** and pusher tube **144**. Other handle embodiments are described in U.S. patent application Ser. No. 11/614,271, the entire contents of which are hereby incorporated by reference.

The slide mechanism **102** translates along calibrated slot **104**. Slide mechanism **102** is coupled with outer sheath **124**. Slide mechanism **102** is adapted to retract the outer sheath **124** a selected distance so that the self-expanding tubular prostheses **128** may be exposed for delivery. As sheath **124** is retracted, the distal most section of prosthesis **128** begins to expand. Additional details on the operation of sheath **124** and pusher **144** are described below. The slide mechanism **102** may include optional visual markers **148** that allow an operator to easily determine the length or number of prostheses that have been exposed. In preferred embodiments, slide mechanism **102** may have detents or a ratchet that provides audible or tactile feedback to the operator to facilitate operation of the stent delivery catheter **50** without requiring direct visualization during operation.

Handle **106** also comprises a second control mechanism **140** that translates along calibrated slot **142**. Slide mechanism **140** is coupled with the pusher tube **144** and is adapted to retract or advance pusher tube **144** independently of outer sheath **124**. Retracting pusher tube **144** allows the number of prostheses **128** to be selected for deployment. Advancement of pusher tube **144** advances the prostheses **128** distally and couples the prostheses **128** together. Slide mechanism **140** may also include optional visual markers **150** that help the physician determine the position of the pusher tube **144** or the number of prostheses **128** selected for deployment or the total length thereof. Additionally, the slide mechanism **140** may comprise detents or a ratchet that further assists physician operation by providing audible or tactile feedback. Further details on operation of the pusher tube **144** and the outer sheath **124** are discussed below.

Handle **106** also permits connection of an external fluid source via adapter **108** attached to the proximal end of handle **106**. Fluid may then be injected at the proximal handle end and infused along a lumen in inner shaft **134** into a patient via distal port **156** or other infusion ports (not shown) near the distal end of the delivery catheter **50**. The adaptor **108**, preferably a Luer connector, is configured to be fluidly coupled with a fluid source such as a syringe or intravenous bag. In alternative embodiments adaptor **108** may be fluidly connected to an inflation lumen **135** in inner shaft **134** which is connected to an optional inflatable balloon (not shown) near the distal end of the catheter **50**. An inflation device which may be any commercially available balloon inflation device such as those sold under the trade name "Indeflator™", manufactured by Abbott (formerly Guidant Corporation of Santa Clara, Calif.) may then be connected to adaptor **108** to deliver an inflation fluid to the balloon.

Additional details on materials and construction of other suitable handles and control mechanisms are described in co-pending U.S. patent application Ser. No. 11/148,713, filed Jun. 8, 2005, entitled "Devices and Methods for Operating and Controlling Interventional Apparatus," and co-pending United States Publication No. 2005/0149159, entitled "Devices and Methods for Controlling and Indicating the Length of an Interventional Element," and application Ser. No. 11/614,271, filed Dec. 21, 2006, formerly 021629-003800US), entitled "Custom Length Stent Apparatus," the full disclosures of which are incorporated herein by reference.

Outer sheath **124** may be composed of any of a variety of biocompatible materials, such as but not limited to a polymer like PTFE, FEP, polyimide, Nylon or Pebax, and may be reinforced with a metallic or polymeric braid to resist radial expansion of self-expanding prostheses **128**. Similar materials may also be used for the inner shaft **134**. Both the inner shaft **134** and outer sheath **124** may also be fabricated from metals such stainless steel or nickel-titanium alloys like nitinol.

Pusher tube **144** is seen in FIG. **1**B. Pusher tube **144** is an elongate tube having a central lumen that is slidably disposed over inner shaft **134** and under outer sheath **124**. The proximal end of pusher tube **144** is coupled with handle **106** as discussed above. The distal end of pusher **144** is adapted to slide under prostheses **128** when pusher **144** is retracted and to engage a prosthesis **128** and move it distally when pusher **144** is advanced distally. The pusher **144** therefore selects the number of prostheses **128** for delivery and provides enough force to interlock prostheses **128** together as will be discussed below. Pusher tube **144** is often an extruded polymer tube, manufactured from similar materials as the outer sheath **124** or inner shaft **134**. The distal tip of pusher **144** typically comprises resilient fingers **166** which may be a polymer or a metal ring with resilient fingers **166** formed from metals such as spring temper stainless steel or nickel-titanium alloy such as nitinol bonded or welded to the distal end of pusher **144**. Pusher tube **144** may also be made from nitinol tubing with resilient fingers on the distal end.

Additional aspects of the luminal prosthesis delivery system are described in U.S. patent application Ser. No. 10/306,813, filed Nov. 27, 2002; U.S. patent application Ser. No. 10/637,713, filed Aug. 8, 2003; U.S. patent application Ser. No. 10/738,666, filed Dec. 16, 2003; and U.S. patent application Ser. No. 11/104,305, filed Apr. 11, 2005; the full disclosures of which are hereby incorporated by reference.

FIG. **1**C illustrates another embodiment of a prosthesis delivery catheter **100** similar to delivery catheter **50** described in FIG. **1**A, except that delivery catheter **100** now comprises a guidewire tube and is not a simple over the wire catheter. Delivery catheter **100** comprises a catheter shaft **120** which includes a sheath **124** slidably disposed over a pusher tube **144** which is in turn slidably disposed over an inner shaft **134** (seen in FIG. **2**A). A prosthesis **126** is carried near the distal end of the catheter shaft **120** and is covered by sheath **124**. Pusher tube **144** is adapted to move past the prosthesis **126** in one direction and to push prosthesis **126** in a second direction as described further below. A tapered nosecone **136** having a distal exit port **156**, composed of a soft elastomeric material to minimize trauma to the vessel during advancement of the delivery catheter **50**, is attached to the inner shaft **134** distally of the prosthesis **126**. Prosthesis **126** preferably comprises a plurality of self-expanding prostheses **128** mounted under sheath **124** and disposed over inner shaft **134**. Sheath **124** covers the self-expanding prostheses **128** and constrains them in a radially contracted configuration until the delivery catheter **100** has been properly positioned at a treatment site. A radiopaque marker **152** (FIG. **2**A) near the proximal end of nosecone **136** or optionally a radiopaque marker **151** near the distal end of sheath **124** and a radiopaque marker **153** near the distal end of pusher tube **144** help the operator visualize the

delivery catheter under a fluoroscope during a stent procedure. Radiopaque marker **153** also helps the operator to view the distance the pusher **144** has been retracted relative to the radiopaque marker **152** adjacent to nosecone **136**. This helps the operator determine how many prostheses **128** to deploy and will be discussed in greater detail below.

A guidewire tube **122** is slidably positioned through sheath **124** and inner shaft **134** proximal to the prosthesis **126**. A guidewire **138** is positioned slidably through guidewire tube **122** and nosecone **136** and exits a distal exit port **156**, extending distally thereof. Additional details on guidewire tube **122** are disclosed in copending U.S. patent application Ser. No. 10/814,581, the entire contents of which are hereby incorporated by reference.

As shown in FIG. **1**C, a handle **106** is attached to a proximal end **112** of the outer sheath **124**. The handle **106** generally takes the same form as handle **106** which was previously described above with reference to FIG. **1**A and controls the movement of outer sheath **124** and pusher tube **144**. FIG. **1**C shows two sliders **102**, **140** used to control sheath **124** and pusher **144**, however, optionally, a single slide mechanism could be used to control motion of the outer sheath **124** and pusher tube **144**. Other handle embodiments are described in U.S. patent application Ser. No. 11/614,271, the entire contents of which have previously been incorporated by reference. Additional details on materials and construction of other suitable handles and control mechanisms have also been described in co-pending U.S. patent application Ser. No. 11/148,713, filed Jun. 8, 2005, entitled "Devices and Methods for Operating and Controlling Interventional Apparatus," as well as co-pending United States Publication No. 2005/0149159, entitled "Devices and Methods for Controlling and Indicating the Length of an Interventional Element," the full disclosures of which are incorporated herein by reference.

Both outer sheath **124** and guidewire **138** each extend through a slider assembly **132** slidably disposed on the catheter body **120** at a point between its handle **106** and prostheses **128**. The slider assembly **132** is adapted for insertion into and sealing with a hemostasis valve, such as on an introducer sheath or guiding catheter, while still allowing relative movement of the outer sheath **124** relative to the slider assembly **132**. The slider assembly **132** includes a slider tube **118**, a slider body **116**, and a slider cap **114**.

Outer sheath **124** may be composed of any of a variety of biocompatible materials, such as but not limited to a polymer like PTFE, FEP, polyimide, Nylon or Pebax, and may be reinforced with a metallic or polymeric braid to resist radial expansion of self-expanding prostheses **128**. Similar materials may also be used for the inner shaft **134**. Both the inner shaft **134** and outer sheath **124** may also be fabricated from metals such as stainless steel or nickel-titanium alloys like nitinol.

Pusher tube **144** is seen in FIG. **2**A. Pusher tube **144** generally takes the same form as pusher **144** in FIG. **1**B and is an elongate tube having a central lumen that is slidably disposed over inner shaft **134** and under outer sheath **124**. The proximal end of pusher tube **144** is coupled with handle **106** as discussed above. The distal end of pusher **144** is adapted to slide under prostheses **128** when pusher **144** is retracted and to engage a prosthesis **128** and move it distally when pusher **144** is advanced distally. The pusher **144** therefore selects the number of prostheses **128** for delivery and provides enough force to interlock prostheses **128** together as will be discussed below. Pusher tube **144** may be fabricated similarly as previously described.

Additional aspects of the luminal prosthesis delivery system are described in U.S. patent application Ser. No. 10/306,813, filed Nov. 27, 2002; U.S. patent application Ser. No. 10/637,713, filed Aug. 8, 2003; U.S. patent application Ser. No. 10/738,666, filed Dec. 16, 2003; and U.S. patent application Ser. No. 11/104,305, filed Apr. 11, 2005; the full disclosures of which are hereby incorporated by reference.

Prosthesis **126** in FIGS. **1**A-**1**C is composed of one or more prostheses **128**. Prostheses **128** are disposed over the inner shaft **134** and under sheath **124**. Each prosthesis or segment **128** has interlocking tabs on each end and is about 3-50 mm in length, more typically about 10-30 mm in length and preferably being about 15-25 mm in length. Usually 2-20, more typically 2-15 and preferably 5-10 prostheses **128** are positioned axially over the inner shaft **134**. Prostheses **128** are preferably positioned with a spacing in between prostheses **128**. The spacing is typically between about 0.5 mm and about 1 mm. During selection and deployment of the prostheses **128**, the prostheses **128** selected for deployment are pressed together so that interlocking tabs engage and the prostheses **128** are coupled together. Thus, prostheses **128** may be deployed individually or in groups of two or more at a single treatment site within the vessel lumen.

In preferred embodiments the adjacent ends have axially extending members that interleave and engage with one another. In an embodiment seen in FIG. **3**A, the geometry of prosthesis **300** is illustrated in an unexpanded configuration, unrolled and flattened out for clarity. In FIG. **3**A, prosthesis **300** comprises eleven substantially parallel columns **302***a*, **302***b*, **302***c*, **302***d*, **302***e*, **302***f*, **302***g*, **302***h*, **302***i*, **302***j*, **302***k* of open cells **326**, spaced apart by a gap **330** and formed around a central axis **324** so that prosthesis **300** has a tubular or cylindrical shape. Each column **302***a*, **302***b*, **302***c*, **302***d*, **302***e*, **302***f*, **302***g*, **302***h*, **302***i*, **302***j*, **302***k* is formed from an undulating or sinusoidal or zig-zag or wave pattern **318**. The wave pattern **318** is comprised of substantially axial struts **320** joined together by a U-shaped connector **322**. The struts **320** are generally parallel to the central axis **324**.

In this embodiment, each wave pattern **318** repeats itself sixteen times in each of the eleven parallel columns **302***a*, **302***b*, **302***c*, **302***d*, **302***e*, **302***f*, **302***g*, **302***h*, **302***i*, **302***j*, **302***k* of open cells **326**, although this number is not intended to be limiting. The number of rows of cells may be increased to provide increased scaffolding of the lumen wall or the number of rows may be decreased to minimize the amount of metal in the prosthesis which contacts the lumen wall. The wave pattern **318** in each column is out-of-phase with the adjacent column, therefore the peak of one wave pattern **318** is adjacent to the trough of a wave **318** pattern in an adjacent column. In addition, the parallel columns **302***a*, **302***b*, **302***c*, **302***d*, **302***e*, **302***f*, **302***g*, **302***h*, **302***i*, **302***j*, **302***k* of open cells **326** are joined together by a sigmoidal shaped connector **328** which joins the ends of U-shaped connector **322** together.

The sigmoidal connector **328** generally attaches to the apex of the U-shaped connector **322**. Also, the sigmoidal shaped connector **328** attaches generally to every fourth U-shaped connector **322**, in each column **302***a*, **302***b*, **302***c*, **302***d*, **302***e*, **302***f*, **302***g*, **302***h*, **302***i*, **302***j*, **302***k*, thus there are four sigmoidal shaped connectors **328** between each column **302***a*, **302***b*, **302***c*, **302***d*, **302***e*, **302***f*, **302***g*, **302***h*, **302***i*, **302***j*, **302***k* of open cells **326**. Additionally, the slope of the sigmoidal shaped connectors **328** generally slopes downward between columns **302***a*, **302***b*, **302***c*, **302***d*, **302***e*, **302***f*, **302***g*, **302***h*, **302***i*, **302***j*, **302***k* of open cells **326**. For example, the sigmoidal shaped connector **328** between column **302***a* and **302***b* is attached to U-shaped connector **322** in column **302***a* at a point generally at the apex of the U-shaped connector **322** and substantially parallel to the axial struts **320**. The sigmoidal connector **328** slopes downward toward the adjacent

U-shaped connector **322** in adjacent column **302***b* and attaches to the adjacent U-shaped connector **322** at a point generally at the apex of U-shaped connector **322** and substantially parallel to the axial struts **320**. The sigmoidal shaped connector **322** between columns **302***b* and **302***c* similarly joins U-shaped connectors **322**, sloping downward. This pattern repeats across the prosthesis **300** so that there are ten sets of sigmoidal shaped connectors **328** with downward slopes. Additionally, sigmoidal shaped connectors **322** are staggered such that across any row of open cells **326**, a sigmoidal shaped connector **322** couples columns of open cells **326** every fourth gap **330**.

Both ends of prosthesis **300** also comprise locking tabs **332** having a narrow neck portion **333** and a wider head portion **335** defined by curved strut **338**. Each locking tab **332** is joined to the body of the prosthesis **300** by an axial strut **340** which join to every fourth U-shaped connector **322** at its apex. Strut **338** defines a U-shape or C-shape with enlarged and rounded tips **337** that define a receptacle **339** therein. In some embodiments, the receptacle **339** may be fitted with an optional radiopaque marker **341** to enhance visibility of the prosthesis under a fluoroscope. A space **342** is disposed between ends of locking tabs **332**, defined by a narrow inlet portion **343** and a wider receiver portion **345** adapted to receive the rounded tip **337** on a locking tab **332** from an adjacent prosthesis **300**. Locking tabs **332** on the opposite end of prosthesis **300** are circumferentially offset with respect to the first end so that adjacent prostheses may interleave and engage with one another. FIG. **3**B illustrates how the ends of prostheses **300** with locking tabs **332** engage one another.

FIG. **3**C illustrates prosthesis **300** of FIGS. **3**A-**3**B in the expanded configuration and interlocked with an adjacent expanded prosthesis **300**. In the expanded configuration, U-shaped connectors **322** deflect outwardly, expanding cells **326**. Struts **320**, while still substantially straight, are no longer horizontal and thus the period of the sinusoidal-like wave pattern forming each cell **326** has increased and become more angular to form more of a zig-zag, thereby increasing the diameter of the prosthesis. Cells **326** which originally appear as a series of horizontally oriented ovals, now appear as a series of triangles or diamonds. Sigmoidal connectors **328** maintain the spacing **330** between columns of cells **318**. Additionally, locking tabs **332** remain coupled between adjacent prostheses **300** even after expansion. FIG. **3**D highlights the coupling of locking tabs **332** between adjacent prostheses **300** after expansion.

FIG. **4**A illustrates another embodiment of a prosthesis **400** in the unexpanded configuration, unrolled and flattened out for clarity. This embodiment is similar to the embodiment in FIGS. **3**A-**3**D with the major difference being that this embodiment has fewer columns of open cells and different interlocking tabs on either end of the prosthesis.

FIG. **4**A shows a preferred embodiment of a prosthesis illustrated in the unexpanded configuration, unrolled and flattened out for clarity. Prosthesis **400** comprises nine substantially parallel columns of **402***a*, **402***b*, **402***c*, **403***d*, **402***e*, **402***f*, **402***g*, **402***h* and **402***i* of open cells **426**, spaced apart by a gap **430** and formed around a central axis **424** so that prosthesis **400** has a tubular or cylindrical shape. Each column **402***a*, **402***b*, **402***c*, **403***d*, **402***e*, **402***f*, **402***g*, **402***h* and **402***i* is formed from an undulating or sinusoidal or zig-zag or wave pattern **418**. The wave pattern **418** is comprised of substantially axial struts **420** joined together by a U-shaped connector **422**. The struts **420** are generally parallel to the central axis **424**.

In this embodiment, each wave pattern **418** repeats itself sixteen times in each of the nine parallel columns **402***a*, **402***b*, **402***c*, **403***d*, **402***e*, **402***f*, **402***g*, **402***h* and **402***i* of open cells **426**, although this number is not intended to be limiting. The number of rows of cells **426** may be increased to provide increased scaffolding of the lumen wall or the number of rows may be decreased to minimize the amount of metal in the prosthesis which contacts the lumen wall. The wave pattern **418** in each column is out-of-phase with the adjacent column, therefore the peak of one wave pattern **418** is adjacent to the trough of a wave **418** pattern in an adjacent column. In addition, the parallel columns **402***a*, **402***b*, **402***c*, **403***d*, **402***e*, **402***f*, **402***g*, **402***h* and **402***i* of open cells **426** are joined together by a sigmoidal shaped connector **428** which joins the ends of U-shaped connector **422** together.

The sigmoidal connector **428** generally attaches to the apex of the U-shaped connector **422**. Also, the sigmoidal shaped connector **428** attaches generally to every fourth U-shaped connector **422**, in each column **402***a*, **402***b*, **402***c*, **403***d*, **402***e*, **402***f*, **402***g*, **402***h* and **402***i*, thus there are four sigmoidal shaped connectors **428** between each column **402***a*, **402***b*, **402***c*, **403***d*, **402***e*, **402***f*, **402***g*, **402***h* and **402***i* of open cells **426**. Additionally, the slope of the sigmoidal shaped connectors **428** generally slopes downward between columns **402***a*, **402***b*, **402***c*, **403***d*, **402***e*, **402***f*, **402***g*, **402***h* and **402***i* open cells **426**. For example, the sigmoidal shaped connector **428** between column **402***a* and **402***b* is attached to U-shaped connector **422** in column **402***a* at a point generally at the apex of the U-shaped connector **422** and substantially parallel to the axial struts **420**. The sigmoidal connector **428** slopes downward toward the adjacent U-shaped connector **422** in adjacent column **402***b* and attaches to the adjacent U-shaped connector **422** at a point generally at the apex of U-shaped connector **422** and substantially parallel to the axial struts **420**. The sigmoidal shaped connector **422** between columns **402***b* and **402***c* similarly joins U-shaped connectors **422**, sloping downward. This pattern repeats across the prosthesis **400** so that there are eight sets of sigmoidal shaped connectors **428** with downward slopes. Additionally, sigmoidal shaped connectors **422** are staggered such that across any row of open cells **426**, a sigmoidal shaped connector **422** couples columns of open cells **426** every fourth gap **330**.

Both ends of prosthesis **400** comprise interlocking tabs. One end of prosthesis **400** has a locking male tab **432** and the opposite end has a female receiving tab **436**. Male tab **432** has a wider head portion **434** defined by arcuate strut **438** unconnected at one end so that it may flex and a narrow neck portion **433** defined by axial strut **436**. Axial struts **436** couple the male locking tab **432** to adjacent U-shaped connectors **422** and therefore there also is a spacing **442** between axial struts **436**. Female receiving tab **436** also has an enlarged head portion **444** and a narrower neck portion **446**. The head portion **444** is formed from arcuate struts **448** shaped like a "C" or a "U," and having bulbous tips **450**. The arcuate struts **448** form a receptacle **454** which is adapted to interlock with the enlarged head portion **434** of male locking tab **432**. The neck portion is formed from a wide strut **452** which joins with adjacent axial struts **420**, replacing the U-shaped connector **422**. Female tabs **436** are staggered relative to male tabs **432** so that adjacent prostheses may interlock with each other. FIG. **4**B illustrates how the ends of prostheses **400** with tabs **432** and **436** engage one another.

FIG. **5**A shows another embodiment of an interlocking prosthesis **500** in the unexpanded configuration, unrolled and flattened out for clarity. This embodiment is similar to that shown in FIGS. **4**A-**4**B with the major difference being the interlocking tabs on either end of the prosthesis **500**. The overall geometry of prosthesis **500** is the same as prosthesis **400** above. For example, prosthesis **500** also has nine substantially parallel columns **502***a*, **502***b*, **502***c*, **502***d*, **502***e*,

502*f*, **502***g*, **502***h* and **502***i* of open cells **526** spaced apart by a gap **530** and formed around a central axis **524** so that prosthesis **500** has a tubular or cylindrical shape. Each column **502***a*, **502***b*, **502***c*, **502***d*, **502***e*, **502***f*, **502***g*, **502***h* and **502***i* has the same undulating wave pattern **418** as prosthesis **400** with a sigmoidal connector **528** coupling the nine columns **502***a*, **502***b*, **502***c*, **502***d*, **502***e*, **502***f*, **502***g*, **502***h* and **502***i* together. Other aspects of the sigmoidal connector **528** are generally the same as sigmoidal connector **428** described above with respect to FIGS. **4**A-**4**B.

Both ends of prosthesis **500** comprise interlocking tabs. One end of prosthesis **500** has a locking male tab **532** and the opposite end has a female receiving tab **536**. Male tab **532** has a wider head portion **534** defined by an arcuate strut **538** forming a "C" shape and having free ends **539** that may flex, and a narrow neck portion **533** defined by an axial strut **536**. The axial strut **536** is coupled with the C-shaped arcuate strut **538** approximately at the center of the concave portion of the "C." The axial strut **536** couples the male locking tab **532** to the prosthesis **500** at the apex of U-shaped connector **522** in open cell **526**. There are four male locking tabs **532** on one end of prosthesis **500**, spaced apart every four rows of open cells **526**.

The opposite end of prosthesis **500** has a female receiving tab **536** which includes an enlarged head portion **544** and a narrower neck portion **546**. The head portion **544** is formed from an arcuate strut **548** shaped like a "C" or a "U," and having enlarged tips **550** defining a receptacle **551** therein. An optional radiopaque marker **553** may be press-fit, welded or bonded into receptacle **551**. Radiopaque markers are commonly fabricated from gold, platinum, iridium or tantalum. The arcuate strut **548** forms another receptacle **554** having a narrow inlet portion **560** and a wider receiver portion **562** which is adapted to interlock with the enlarged head portion **534** of male locking tab **532**. The neck portion **546** is formed from a strut **552** which joins with the adjacent axial struts **520** which form open cells **526**. Strut **552** joins with strut **520** at the apex of U-shaped connector **522**. Female receiving tabs **536** are staggered with respect to male tabs **532** so that adjacent prostheses **500** may interlock with each other. Prostheses **500** interlock with one another by pressing them together. FIG. **5**B illustrates how the ends of prostheses **500** with tabs **532** and **536** engage one another.

Other interleaving stent embodiments are described in copending U.S. patent application Ser. No. 10/738,666 filed Dec. 16, 2003; U.S. patent application Ser. No. 10/957,079 filed Sep. 30, 2004; and U.S. Provisional Application No. 60/784,309 filed Mar. 20, 2006, the entire contents of which are incorporated herein by reference.

Prostheses **128** are preferably composed of an elastic or superelastic shape memory alloy such as Nitinol so that the prostheses **128** resiliently self-expand upon release into a vessel by retraction of the sheath **124**. Other possible materials include a spring temper metal such as stainless steel, cobalt-chromium or ELGILOY™ so the prostheses **128** may self-expand in the body lumen at the target treatment site. In the case of self-expanding prostheses **128**, an inflation balloon is not required but may still be used for predilation of a lesion or augmenting expansion of the self-expanding stent segments **128** (e.g. postdilation or tacking). Other materials such as biocompatible polymers may be used to fabricate prosthetic stent segments that self-expand, and these materials may further include bioabsorbable or bioerodable properties.

In other embodiments, prostheses **128** may have any of a variety of common constructions, such as but not limited to those described in U.S. patent application Ser. No. 10/738,666 filed Dec. 16, 2003, which was previously incorporated by reference. Constructions may include for example, closed cell constructions including expansible ovals, ellipses, box structures, expandable diamond structures, etc. In addition, the closed cells may have complex slotted geometries such as H-shaped slots, I-shaped slots, J-shaped slots, etc. Suitable open cell structures include zig-zag structures, serpentine structures, and the like. Such conventional stent structures are well described in the patent and medical literature. Specific examples of suitable stent structures are described in the following U.S. patents, the full disclosures of which are incorporated herein by reference: U.S. Pat. Nos. 6,315,794; 5,980,552; 5,836,964; 5,527,354; 5,421,955; 4,886,062; and 4,776,337.

In preferred embodiments, prosthetic stent segments **128** may be coated, impregnated, infused or otherwise coupled with one or more drugs that inhibit restenosis, such as Rapamycin, Everolimus, Biolimus A9, Paclitaxel, analogs, prodrugs, or derivatives of the aforementioned, or other suitable agents, preferably carried in a durable or bioerodable carrier of polymeric or other suitable material. Alternatively, stent segments **128** may be coated with other types of drugs or therapeutic materials such as antibiotics, thrombolytics, antithrombotics, anti-inflammatories, cytotoxic agents, anti-proliferative agents, vasodilators, gene therapy agents, radioactive agents, immunosuppressants, chemotherapeutics, endothelial cell attractors or promoters and/or stem cells. Such materials may be coated over all or a portion of the surface of stent segments **128**, or stent segments **128** may have a porous structure or include apertures, holes, channels, or other features in which such materials may be deposited.

Referring now to FIGS. **2**A-**2**E, the deployment of selected prostheses to treat a lesion is shown in accordance with an exemplary embodiment. While the embodiment will be described in the context of a femoral artery stent procedure, it should be understood that the invention may be employed in any variety of coronary or peripheral arteries, blood vessels and other body lumens in which stents or tubular prostheses are deployed, including the carotid and iliac arteries, other arteries or veins, as well as non-vascular body lumens such as the ureter, urethra, fallopian tubes, the hepatic and biliary duct and the like. The delivery catheter is introduced into a treatment vessel first, by placing an introducer sheath (not illustrated) into the target peripheral artery, typically using a percutaneous procedure such as the Seldinger technique or by surgical cutdown. In this exemplary embodiment, the target vessel is a femoral artery. The introducer sheath is then advanced slightly into the femoral artery. A guidewire **138** is then inserted through the introducer and advanced into the target vessel V where a lesion L to be treated is located. The proximal end of guidewire **138** is then inserted through distal port **156** of nosecone **138** and through inner lumen **135** of inner shaft **134**, exiting handle **106** at adapter **108** which is outside the patient's body. Optionally, a guide catheter may also be employed.

FIG. **2**A shows a stent delivery catheter **200** slidably advanced over the guidewire **138** into the vessel V so that nosecone **138** is distal to lesion L. Self-expanding tubular prostheses **128** having ends spaced apart are disposed over inner shaft **134** and constrained by outer sheath **124**. In this embodiment, four prostheses **128** are carried by the stent delivery catheter **200**, although this is not intended to be limiting. The number of prostheses may be varied to accommodate different lesion lengths.

Outer sheath **124** has a high hoop strength near the distal end such that the outer sheath **124** is able to prevent the self-expanding prostheses **128** from expanding when the

outer sheath **124** is disposed thereover. This may be accomplished by using an outer sheath **124** with a suitable wall thickness or the sheath **124** may also have a distal portion formed from a metal or polymer reinforced with a metallic or polymeric braid to resist radial expansion of the self-expanding prostheses **128**.

In this embodiment, each prosthesis **128** has a length approximately 20 mm long. Thus the delivery catheter **200** is adapted to deliver a prosthesis having a total length from about 20 mm long, up to 80 mm long, in 20 mm increments. Other lengths and quantities of prostheses **128** may be employed and this exemplary embodiment is not meant to limit the scope of the present invention.

Radiopaque marker **152** is disposed near the proximal end of nosecone **138** or alternatively, radiopaque marker **152** may be disposed on inner shaft **134** near the proximal end of nosecone **138**. Radiopaque marker **153** is disposed near the distal end of pusher **144**. Radiopaque markers are typically fabricated from gold, platinum, iridium or tantalum and are well known in the art. Radiopaque markers **152** and **153** help an operator to visualize the tip of delivery catheter **200** under fluoroscopy as well as determining the number of prostheses **128** to deploy to traverse the lesion L. In some embodiments, an optional radiopaque marker **151** may be disposed near the distal end of outer sheath **124** so that sheath position may also be observed under fluoroscopy. Pusher tube **144** is also seen in FIG. **2**A disposed over inner shaft **134**. The distal end pusher tube **144** comprise several resilient fingers **166** which radially extend outward such that pusher tube **144** may be retracted proximally past prostheses **128** but when pusher **144** is advanced distally, the resilient fingers **166** engage a prosthesis **128** so that the prosthesis **128** is advanced distally as the pusher **144** is advanced. Distal motion of prosthesis **128** allows adjacent prostheses **128** having interlocking tabs **162** to engage with receptacle **164**, eliminating gap **160**. Pusher tube **144** also serves as a backstop to prevent proximal motion of prostheses **128**. Additional details on these elements will be discussed in greater detail below, with respect to FIGS. **2**B-**2**E.

Referring now to FIG. **2**B, the lesion L to be treated is typically visualized by introducing contrast media into the target vessel V and observing the resulting image under a fluoroscope. Radiopaque markers **152**, **153** and optional radiopaque marker **151** are used to help visualized the position of the delivery catheter **200** relative to the lesion L as well as to visualize the length of prostheses **129** selected for deployment relative to the target lesion L. Radiopaque marker **152** is typically disposed near the proximal end of nosecone **136** but in alternative embodiments marker **152** may also be disposed on the inner shaft **134** near the proximal end of nosecone **136**. Delivery catheter **200** is advanced until radiopaque marker **152** is near the distal edge of lesion L. Pusher **144** will later be retracted proximally until it is near the proximal end of lesion L. The lesion therefore traverses the region between radiopaque markers **152** and **153**. An optional radiopaque marker **151** disposed near the distal end of outer sheath **124** allows the user to observed sheath position during the stenting procedure.

In FIG. **2**B, pusher tube **144** is retracted proximally until radiopaque marker **153** is near the proximal edge of lesion L. The distal end **166** pusher tube **144** comprises a plurality of resilient, radially extending inclined fingers **166**, thus pusher tube **144** may be retracted proximally under prostheses **128** without displacing them. Retracting pusher **144** selects the number of prostheses **129** to be deployed and that will provide a total prosthesis **126** length that traverses the length of lesion L. Pusher **144** tube extends to the proximal end of delivery catheter **200** and retraction of pusher tube **144** is accomplished using a control mechanism such as slider **140** in FIG. **1**A or **1**C.

In FIG. **2**C, prostheses **129** are advanced distally until they engage and interlock with one another. Pusher tube **144** is advanced distally until it engages the proximal-most end of the proximal prosthesis **129** selected for delivery. The distal end of pusher tube **144** has resilient and radially extending inclined fingers **166**. Advancing pusher tube **144** distally causes the fingers **166** to engage with the proximal-most prosthesis **129** selected for delivery. Further advancement of pusher tube **144** advances the selected prostheses **129** until the distal-most prosthesis **129** of those selected butts up against the proximal end of nose cone **136**. Nosecone **136** has a recessed region **145** in which interlocking tab **162** may be received so that the distal-most prosthesis **129** can fit flush against nosecone **136**. As pusher tube **144** is advanced, prostheses **129** selected for deployment bunch up together until locking tabs **162** engage and interlock with receivers **164** on an adjacent prosthesis **129**. The gap **160** that existed between prostheses **128** prior to deployment therefore is reduced significantly to a slight gap or no gap **161** as prosthesis **129** ends are engaged with one another during deployment. Additionally, if after pushing prostheses **129** together, a longer total length is required, the steps illustrated in FIGS. **2**B-**2**C may be repeated in order to create a longer "stent train."

In FIG. **2**D, the constraint covering prostheses **129** selected for deployment is removed. In FIG. **2**D, outer sheath **124** is retracted proximally. Retraction of outer sheath **124** is accomplished using a control mechanism such as slider **102** in FIG. **1**A or **1**C. Retracting outer sheath **124** removes the constraint and exposes prostheses **129**, allowing them to self-expand into lesion L. As outer sheath **124** is retracted, the exposed portion of prostheses **129** self-expand to a final shape **137** matching lesion L. Prosthesis **129** is prevented from jumping or "watermelon seeding" away from delivery catheter **200** because the prosthesis **129** being deployed is interlocked with an adjacent prosthesis **129** maintained in the delivery catheter **200** and constrained by outer sheath **124**. The position of the outer sheath **124** may be monitored by the operator by visualizing an optional radiopaque marker **151** on the distal end of outer sheath **124**, or the operator may determine sheath position by observing the position of slider **102**. Pusher tube **144** also serves as a backstop to prevent proximal displacement of prostheses **129** that might occur as a result of outer sheath **124** passing distally thereover.

In FIG. **2**E, outer sheath **124** is retracted proximally until all prostheses **129** selected for deployment are unconstrained and they self-expand into the lesion L. If an additional prosthesis **128** is required to treat the lesion L, the pusher tube **144** may be retracted proximally so as to select an additional prosthesis **128** and it may be deployed in similar manner to that previously described. Once all prostheses **129** have been deployed, outer sheath **124** may be advanced distally until it engages nosecone **136** and the entire delivery catheter **200** may be removed from the treatment site. Alternatively, inner shaft **134** may be retracted into outer sheath **124** until nosecone **136** engages outer sheath **124** and then the entire delivery catheter **200** may be withdrawn.

While the exemplary embodiments have been described in some detail for clarity of understanding and by way of example, a variety of additional modifications, adaptations and changes may be clear to those of skill in the art. Hence, the scope of the present invention is limited solely by the appended claims.

What is claimed is:

1. A method for delivering a prosthesis to a body lumen, the method comprising:

introducing into the body lumen one or more self-expanding tubular prostheses carried at axially spaced apart locations along an elongate flexible member, the self-expanding tubular prostheses being axially separated and unlocked within a sheath and constrained in a contracted configuration within the sheath, the body lumen having a lesion with a lesion length;

selecting a first group of the self-expanding tubular prostheses for delivery by proximally retracting a pusher member disposed proximal of the first group of prostheses, the first group of prostheses having a combined length that substantially traverses the lesion length;

distally advancing the pusher member to axially translate the selected first group of prostheses within the sheath to bring the first group of prostheses into locking engagement with each other within the sheath; and

uncovering the first group of prostheses from the sheath so that they are unconstrained from expansion, wherein the first group expands at the first treatment site.

2. The method of claim **1**, wherein the first group expands at the first treatment site while at least a second group of prostheses is retained within the sheath.

3. The method of claim **1**, further comprising:

selecting one or more additional self-expanding tubular prostheses; and

bringing the additional self-expanding tubular prostheses into engagement with the first group within the sheath so that the additional prostheses interlock with the first group.

4. The method of claim **1**, wherein the pusher member has a flexible engagement member that is deflected by the prostheses as the pusher member is retracted proximally.

5. The method of claim **4**, wherein the flexible engagement member comprises a plurality of resilient fingers.

6. The method of claim **5**, wherein each of the plurality of resilient fingers extend radially away from the pusher member, and wherein one or more of the plurality of resilient fingers engages a proximal-most prosthesis of the first group when advanced distally to bring the first group into engagement with each other.

7. The method of claim **1**, wherein axially translating the at least one prosthesis comprises engaging the prosthesis with a flexible engagement member disposed on the pusher member.

8. The method of claim **1**, further comprising stopping the first group of prostheses from moving distally with a stopping element disposed on the elongate flexible member.

9. The method of claim **1**, wherein uncovering the first group comprises proximally retracting the sheath.

10. The method of claim **1**, further comprising releasing a therapeutic agent from the first group after expansion at the treatment site.

11. The method of claim **10**, wherein the therapeutic agent comprises an anti-restenosis agent.

12. The method of claim **1**, wherein the plurality of self-expanding tubular prostheses have a length in the range of about 5 mm to about 50 mm.

13. The method of claim **1**, wherein each of the plurality of self-expanding tubular prostheses has the same length.

14. The method of claim **1**, wherein at least one of the plurality of self-expanding tubular prostheses has a different length than at least another of the prostheses.

15. The method of claim **1**, wherein the prosthesis comprises a plurality of substantially parallel columns of open cells, the columns spaced apart and formed from a zig-zag pattern of substantially axial struts joined together with a connector.

16. The method of claim **15**, wherein the connector comprises a U-shaped portion.

17. The method of claim **15**, wherein the open cells in a first column are out of phase with the open cells in an adjacent column.

18. The method of claim **1**, wherein a plurality of bridges join the columns of open cells together.

19. The method of claim **18**, wherein the bridges are sigmoidally shaped.

20. The method of claim **1**, wherein a prosthesis comprises an interlocking tab disposed on a first end of the prosthesis and adapted to interlock with an adjacent prosthesis.

21. The method of claim **20**, wherein the prosthesis comprises a mating tab disposed on a second end of the prosthesis opposite the first end, the mating tab adapted to interlock with an interlocking tab on an adjacent prosthesis.

22. The method of claim **20**, wherein the interlocking tab comprises one or more struts defining an aperture therein.

23. The method of claim **20**, wherein the interlocking tab comprises a radiopaque marker.

24. The method of claim **1**, wherein the interlocked prostheses prevent the prostheses from jumping away from the elongate flexible member when the first group is unconstrained.

25. The method of claim **1**, wherein each of the prostheses comprises a distal U-shaped interlocking member and a proximal U-shaped interlocking member, and wherein the first group of prostheses are interlocked by mating distal U-shaped interlocking members and proximal U-shaped interlocking members of adjacent prostheses.

26. The method of claim **1**, wherein the elongate flexible member comprises a radiopaque marker at a distal end of the elongate flexible member, and wherein the pusher member disposed within the elongate flexible member comprises a radiopaque marker at a distal end of the pusher member, the method further comprising:

retracting the pusher member proximally to select the first group of prostheses; and

bringing the first group of prostheses into engagement with each other by advancing the pusher member distally, wherein the radiopaque marker at the distal end of the elongate flexible member and the radiopaque marker at the distal end of the pusher member facilitate in selecting the first group of prostheses so that the combined length of the first group substantially traverses the lesion length.

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